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09/927,914	08/10/2001	Timothy P. Tully	21RE-137270	5180
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DON J. PELTO				
Sheppard, Mullin, Richter & Hampton LLP				
1300 I STREET, NW				
11TH FLOOR EAST				
WASHINGTON, DC 20005				
EXAMINER				
CHONG, YONG SOO				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No. 09/927,914	Applicant(s) TULLY ET AL.
Examiner Yong S. Chong	Art Unit 1627

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 June 2010 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☐ The period for reply expires _____ months from the mailing date of the final rejection.
b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☐ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.
NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).

5. ☐ Applicant's reply has overcome the following rejection(s): _____.

6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 1,4-8,100-104,107 and 108.

Claim(s) withdrawn from consideration: 2,9,10,12,13,21,22,24-48,59 and 65-93.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).

9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).

10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:
See Continuation Sheet.

12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____

13. ☐ Other: _____.

/Yong S. Chong/
Primary Examiner, Art Unit 1627

Continuation of 11, does NOT place the application in condition for allowance because: Applicant's arguments have been fully considered but found not persuasive for reasons of record. Specifically, Applicant request to withdraw the claim objection and 112 rejection is denied because the claim amendments have not been entered into record. Applicant is reminded that prosecution is now closed.

Applicant argues that the prior art does not teach or suggest administering a PDE4 inhibitor in conjunction with cognitive training. Christensen does not administer PDE4 inhibitors after the acute phase of stroke. Christensen does not expressly or inherently disclose administering a PDE4 inhibitor during rehabilitation of a stroke patient. Specifically, Applicants go into great detail regarding the mechanism of action of PDE4 inhibitors, including inhibiting the inflammatory response often associated during the immediate time period following a brain injury. Therefore, Christensen effectively teaches away from the repeated application of PDE4 inhibitors in conjunction with stroke, due to the early production of TNF during the initial stages of an inflammatory event.

This is not persuasive because Christensen clearly does not limit the administration of PDE4 inhibitors to any particular time period or treatment window of a stroke patient. In fact, Christensen clearly recites the treatment of a stroke patient, which also includes the time after the acute phase of stroke episode or the rehabilitation period involving cognitive training. One of ordinary skill in the art would interpret the teachings of Christensen to administer the PDE4 inhibitor after the acute phase of stroke episode since a full clinical diagnosis must be made before any treatment regimen is to be implemented. The skilled artisan would also recognize that rehabilitation should be started as soon as a full diagnosis is made. Further, it is not clear when exactly does inflammation subside during the treatment period of a stroke patient, since low levels of inflammation could last well into the rehabilitation period. Applicant is reminded that the standard for obviousness is not absolute but a reasonable expectation of success.

Applicant argues against the Examiner's response in that this arguments is no longer applicable because the pending claims clearly limit administration of PDE4 inhibitors and cognitive training to the rehabilitation phase. Again, this is assuming that the claim amendments have been entered into record, which it has not since prosecution is now closed.

Applicant also argues that the Merck Manual can only be read to teach cognitive training after the acute phase of a stroke. As a result, Applicant argues against the motivation in the obviousness rejection.

This is not persuasive because as stated above, Christensen clearly teaches, in general, the treatment of a stroke patient by administering a PDE4 inhibitor, which encompasses the entire treatment regimen including rehabilitation. Furthermore, the Merck Manual clearly state that a training protocol should be started as early as possible towards a patient's rehabilitation to stroke. Such rehabilitation includes encouragement, orientation toward the outside environment, eating, dressing, toilet functions, other basic needs, passive exercise, particularly of paralyzed limbs, and breathing exercises, if possible, should be started early. This time period may encompass when the patient is still in or just recovering from the acute phase of the stroke episode and beyond. Nonetheless, it is clear that the Merck Manual teaches cognitive training after the acute phase of a stroke. It is Examiner's position that it would be obvious to administer PDE4 inhibitors as taught by Christensen in combination with rehabilitation after the acute phase of stroke. Therefore, since both references teach treating stroke patients, it is obvious to combine these treatment regimens because both are drawn to the same purpose as well as for the combined therapeutic effect. For these reasons, Examiner submits that there would be reasonable expectation of success in treating stroke patients as instantly claimed. Applicant's arguments directed to two different treatments, whose roles in stroke are mechanically, temporally, and clinically distinct, are not persuasive. The reason being that although the mechanism of action may be different, the ultimate goal of treating stroke is the same. It is Examiner's position that both treatment regimens serve to work together in treating a stroke patient through rehabilitation.

Finally, Applicant propose the following amendment on page 21 of the response. Examiner respectfully declines examining proposed amendments because prosecution is now closed. Applicant claims that the claim amendments would exclude patients that have not received a PDE4 inhibitor for the purpose of augmenting cognitive training during rehabilitation. Such claims would therefore exclude the prophetic patients treating in Christensen, who are not being administered PDE4 inhibitors for the purpose of augmenting cognitive training. This is the very reason why these claim amendments are not being entered into record. These claim amendments would require a new consideration and a new search.